



*United States Department of*  
**Health & Human Services**  
Office of the Assistant Secretary for Preparedness and Response



# **National Vaccine Advisory Committee (NVAC)**

## **Bar Code Briefing September 11, 2012**

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# Changes to Bar Code Labeling

- Current FDA Requirement:
  - National Drug Code (NDC) # in one-dimensional bar code
  - Alpha-numeric and bar code
  - printed on primary container and secondary carton
- Future changes driven by the State of California with FDA Concurrence & Support
  - California ePedigree law implementation: 2015-2016
- Primary Objectives:
  - *Medicinal Safety*
  - *Supply Chain Security*
  - *Anti-Counterfeiting*
- Interoperability, Authentication, Data Management



# Current NDC Example



010030182100019

(above) UPC NDC code on Goldline Acetaminophen  
(below) Code 128 equivalent

# Anti-Counterfeit vs. Track & Trace

- U.S. law defines **Counterfeit drugs**:
  - Sold under a product name without proper authorization
  - Identity: Drug source mislabeled, suggests that it is the authentic approved product
  - Brand name, generic products, or bulk ingredients
  - Active Ingredient: Lacking, Insufficient, or Incorrect
  - Packaging: Falsely suggests manufactured by the FDA-approved manufacturer.
  - Consumer fraud: Representing genuine FDA-approved product
- Considered illegal and unsafe
- Visually indistinguishable from authentic drugs
- Unprecedented attack from a variety of increasingly sophisticated threats.
- **Track & Trace**: Process of determining the current and past locations (and other information) of a unique item or property

# ePedigree

- Must be **electronic record** , tracking the **trade image** from sale by manufacturer to sale by pharmacy, maintained in an **interoperable electronic system**, and be **uniquely identifiable**
- 50% of drugs to be implemented by 1 Jan 2015, remaining 50% by 1 Jan 2016
- Most manufacturers are on board and support these efforts as they should help reduce counterfeits and aid recovery of stolen pharmaceuticals
- Leverage of manufacturers' and distributors' Enterprise Resource Planning (ERP) systems

# Technical Solutions



## Standards

Enabling you to identify, capture and share value chain information globally

### Identify



### Capture

GS1 System Data Carriers  
Barcodes and EPC-enabled RFID tags



### Share



# GS1 – Standard Setting Organization

- Non-profit global standards organization to improve efficiency and visibility of supply and distribution chains
  - Global Trade Item Number (GTIN)
    - 14 digit number, coding company and item reference
    - NDCs likely to encode to GTINs
  - Serialization Code
    - Unique 20 digit serial number
    - Assigned by the manufacturer
  - GS1 standard 2-Dimensional (2D) Datamatrix barcode
    - Worldwide standard
    - Can code up to 64 characters:
      - GTIN, serialization code, expiration date, lot number
      - 7x7mm square or 4.25x12.5mm rectangle
    - Includes up to 35% error correction
- All GS1 Standards conform to ISO Standards

# Decode of GS1 Datamatrix

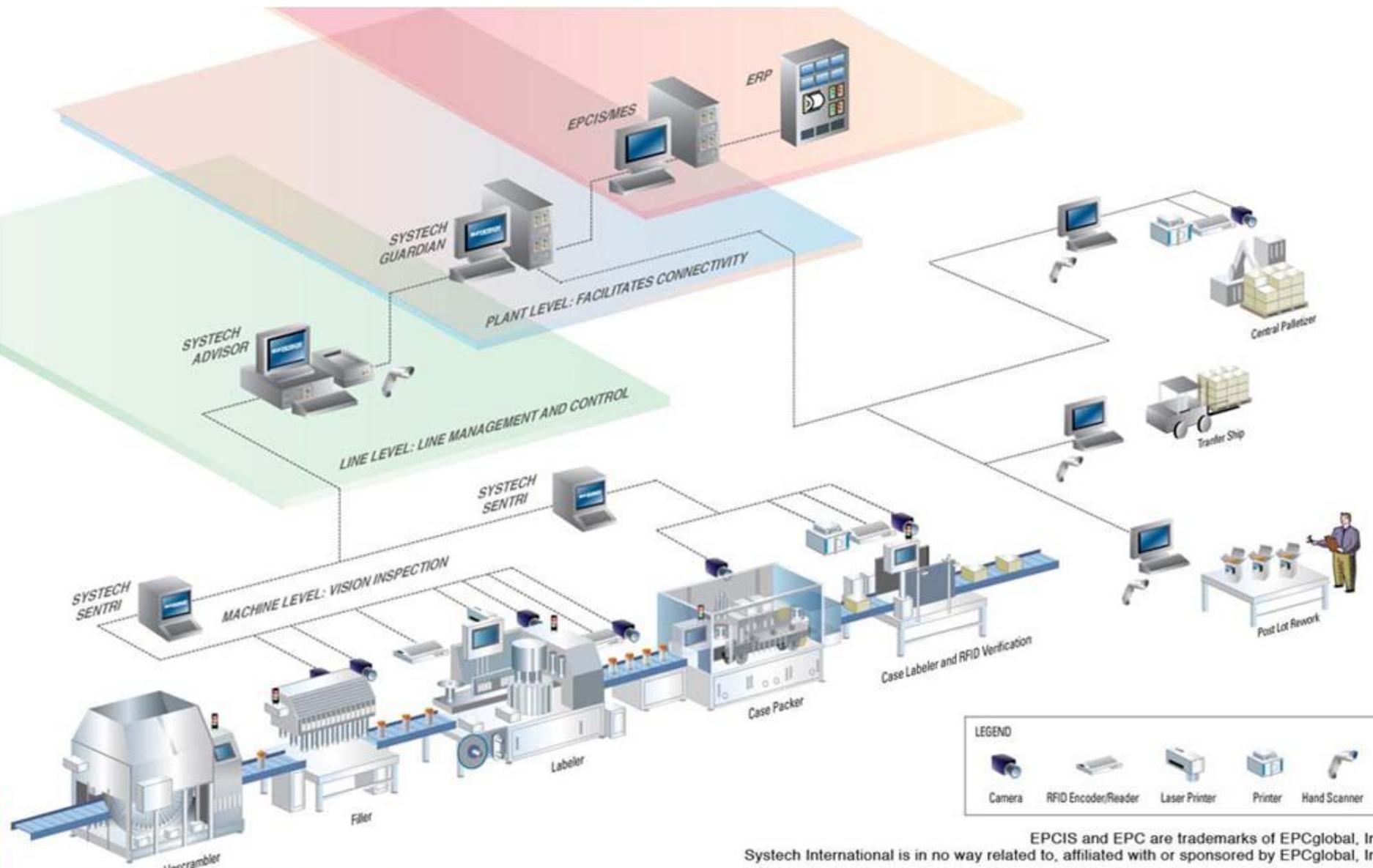
- GTIN: 00112345000017
- Expiration Date:  
110518 (18 May 2011)
- Serial Number:  
01234567890123456789
- Lot Number: UP071AA



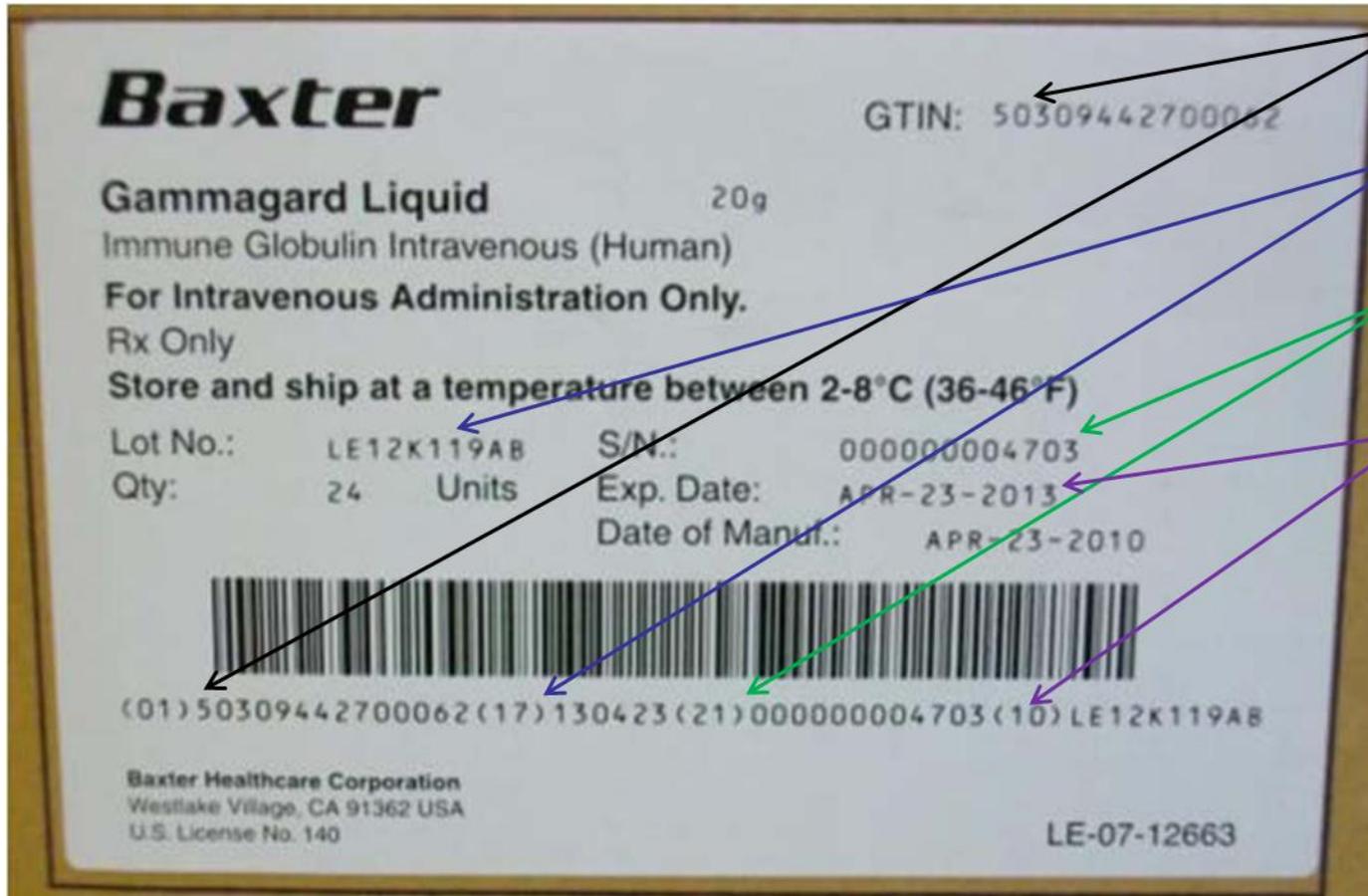
# Current Vaccine Package Elements

- FDA Regulated
  - Primary container label
    - “Real estate” limited – NDC#, bar code, Proprietary name, Non-proprietary name, Lot #, expiry date, contents, storage statement, government license #, manufactured by:
  - Secondary package (carton) – Same as primary container plus further enhancements
  - Package insert
- Unregulated Packaging / Shipping components
  - Packer roll end label – Critical to distributors
  - Pallet identification - Critical to distributors
  - Materials associated w/ shipping –Bills of Lading, Manifests

# Example Assembly Line with Serialization



# GS1 Compatible Case Label



AI(01) GTIN

AI(17) Lot #

AI(21) Serial #

AI(10) Expiration Date

# Unit-of-sale label printing



# Unit-of-sale Label Camera Inspection



# Unit-of-Sale Package Commissioning



# Case Label Printing

